

Evaluation Report for Category L, Subcategory 1.1 Application

Application Number: 2019-3672

Application: Submission Subject to Protection of Proprietary Interests in

Pesticide Data Policy – Equivalency/Data Compensation

Assessment

Product: Sharda Spirodiclofen Technical

Registration Number: #####

Active ingredient (a.i.): Spirodiclofen PMRA Document Number: 3171549

Purpose of Application

The purpose of this application was to register a new source of spirodiclofen, by a new registrant.

Chemistry Assessment

Common Name: Spirodiclofen

IUPAC* Chemical Name: 3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4.5]dec-3-en-4-yl 2,2-

dimethylbutyrate

CAS† Chemical Name: 3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4.5]dec-3-en-4-yl 2,2-

dimethylbutanoate

Sharda Spirodiclofen Technical has the following properties:

Property	Result
Colour and physical state	White solid
Nominal concentration	99.5 %
Odour	characteristic odour
Density	1.2902 g/mL
Vapour pressure	7.72 x 10 ⁻⁴ Pa
pН	6.3 (1 % aqueous solution)
Solubility in water	0.05 mg/L at 20°C



^{*} International Union of Pure and Applied Chemistry

[†] Chemical Abstracts Service

Property	Result
n-Octanol/water partition coefficient	$\log K_{\rm ow} = 5.24$

The required chemistry data for Sharda Spirodiclofen Technical have been provided, reviewed, and found to be acceptable.

Health, Environmental, and Value Assessments

Health, environmental, and value assessments were not required for this application.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the registration of Sharda Spirodiclofen Technical.

References

PMRA Document Number	References
3018207	2016, Spirodiclofen Technical: Determination of The Physico-Chemical Properties, DACO: 2.14.1,2.14.11,2.14.12,2.14.15,2.14.2,2.14.3,2.14.4,2.14.6, 2.14.7,2.14.8,2.14.9
3018208	2015, Spirodiclofen Technical: Complete Analysis of Five Batch Samples, DACO: 2.13.1,2.13.2,2.13.3,2.13.4 CBI
3018209	2015, Spirodiclofen Technical: Spectroscopic Characterization of Five Batch Samples, DACO: 2.13.2,2.13.3 CBI
3018211	2016, Spirodiclofen Technical: Validation of The Analytical Method For The Determination of [CBI removed] as Residual Solvent, DACO: 2.13.1,2.13.4 CBI
3018212	2016, Spirodiclofen Technical: Validation of The Analytical Method For The Determination of The Active Ingredient Content, DACO: 2.13.1
3018214	2015, Spirodiclofen Technical: Validation of The Analytical Method For The Determination of The Relative Impurity Content, DACO: 2.13.1,2.13.4
3018215	2015, Spirodiclofen Technical: Validation of The Analytical Method For The Determination of [CBI removed] as a Relative Impurity Content, DACO: 2.13.1,2.13.4 CBI
3018216	2016, Spirodiclofen Technical: Validation of The Analytical Method For The Determination of [CBI removed] as Relevant Impurity Content, DACO: 2.13.1,2.13.4 CBI
3018217	2016, Spirodiclofen Technical: Analysis of Five Batch Samples For [CBI removed] as Residual Solvent Content And [CBI removed] as Relevant Impurity Content, DACO: 2.13.3,2.13.4 CBI
3018218	2015, Spirodiclofen Technical: HPLC/MS/DAD Screening for Impurities Content in Five Batch Samples, DACO: 2.13.3,2.13.4 CBI
3018219	2016, Spirodiclofen Technical: Determination of The Accelerated Storage Stability And Corrosion Characteristics, DACO: 2.14.13,2.14.14
3091828	2020, Spirodiclofen Technical: Validation of the Analytical Method for the Determination of [CBI removed] Residual Solvent Content, DACO: 2.13.1,2.13.2 CBI
3091830	2020, Spirodiclofen Technical: Complete Analysis of Five Batch Samples, DACO: 2.13.2,2.13.3,2.13.4 CBI
3166057	2020, Determination of [CBI removed] in 5 batches of Spirodiclofen Technical, DACO: 2.13.3,2.13.4 CBI
3168319	2020, The Manufacturing Process of Spirodiclofen - Revised, DACO: 2.11.1,2.11.2,2.11.3,2.11.4 CBI

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